

AMENDED IN SENATE APRIL 17, 2001

AMENDED IN SENATE APRIL 4, 2001

SENATE BILL

No. 340

Introduced by Senator Speier

February 20, 2001

An act to amend Section 4301 of, and to add Sections ~~4073.5~~ 4052.5 and 4126 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 340, as amended, Speier. Pharmacies.

(1) Existing law, the Pharmacy Law, authorizes a pharmacist filling a prescription order for a drug product prescribed by the trade or brand name to substitute a generic drug product, subject to specified requirements.

This bill would authorize a pharmacist to substitute a drug product with a different ~~dosage~~ form *of medication* having the same active chemical ingredients ~~of the same strength and quantity, of equivalent strength and duration of therapy,~~ as the prescribed drug product, unless the prescriber indicates no substitution may be made, *if the change is in the patient's best interest*. The bill would require that the patient be notified of the substitution.

(2) The Pharmacy Law authorizes specified nonprofit and free clinics licensed by the California State Board of Pharmacy to purchase drugs at wholesale for administration or dispensing to patients registered for care at the clinic.

This bill would authorize specified entities, as defined by federal law, to contract with a pharmacy to provide pharmacy related services to patients of the entity. The bill would authorize a pharmacy to dispense

preferentially priced drugs obtained pursuant to federal law, would require that those drugs be segregated from the pharmacy's other drug stock, and would require excess drug stock to be returned to the distributor. The bill would also require pharmacy records of acquisition and disposition of the drugs to be separate from other records. This bill would exclude covered entities and pharmacies from the requirement that they obtain a wholesaler's license for actions necessary to participate in the drug purchase program.

(3) The Pharmacy Law requires the board to take disciplinary action against any person licensed under the Pharmacy Law who is guilty of unprofessional conduct.

The bill would provide that it is unprofessional conduct for any person licensed under the Pharmacy Law to sell, trade, transfer, or furnish, drugs obtained pursuant to federal law, to any person a licensee knows or reasonably should know is not a patient of a covered entity, as defined by federal law.

(4) Because a knowing violation of the Pharmacy Law is a misdemeanor, this bill would expand the scope of that crime and thus would impose a state-mandated local program.

(5) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section ~~4073.5~~ 4052.5 is added to the Business
 2 and Professions Code, to read:
 3 ~~4073.5.~~
 4 4052.5. (a) A pharmacist filling a prescription order for a
 5 drug product ~~prescribed by its trade or brand name~~ may select
 6 ~~another drug product with a different dosage form of medication~~
 7 ~~with the same active chemical ingredients of the same strength and~~
 8 ~~quantity, of equivalent strength and duration of therapy, as the~~
 9 ~~prescribed drug product if the change is in the best interest of the~~
 10 ~~patient.~~

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, “Do not substitute” or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked “Do not substitute” if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). ~~The person~~ *pharmacist* who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed ~~dosage~~ *form of medication*. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the ~~drug product with a different dosage~~ *form of medication* shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

SEC. 2. Section 4126 is added to the Business and Professions Code, to read:

4126. (a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those clinics and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy’s other drug stock by either physical or electronic means. All records of acquisition and

1 disposition of these drugs shall be readily retrievable in a form
2 separate from the pharmacy's other records.

3 (c) Drugs obtained by a pharmacy to be dispensed to patients
4 of a covered entity pursuant to Section 256b of Title 42 of the
5 United States Code that cannot be distributed because of a change
6 in circumstances for the covered entity or the pharmacy shall be
7 returned to the distributor from which they were obtained. For the
8 purposes of this section, a change in circumstances includes, but
9 is not limited to, the termination or expiration of the contract
10 between the pharmacy and the covered entity, the closure of a
11 pharmacy, disciplinary action against the pharmacy, or closure of
12 the covered entity.

13 (d) A licensee that participates in a contract to dispense
14 preferentially priced drugs pursuant to this section shall not have
15 both a pharmacy and a wholesaler license.

16 (e) Neither a covered entity nor a pharmacy shall be required
17 to obtain a license as a wholesaler based on acts reasonably
18 necessary to fully participate in the drug purchase program
19 established by Section 256b of Title 42 of the United States Code.

20 SEC. 3. Section 4301 of the Business and Professions Code
21 is amended to read:

22 4301. The board shall take action against any holder of a
23 license who is guilty of unprofessional conduct or whose license
24 has been procured by fraud or misrepresentation or issued by
25 mistake. Unprofessional conduct shall include, but is not limited
26 to, any of the following:

27 (a) Gross immorality.

28 (b) Incompetence.

29 (c) Gross negligence.

30 (d) The clearly excessive furnishing of controlled substances in
31 violation of subdivision (a) of Section 11153 of the Health and
32 Safety Code.

33 (e) The clearly excessive furnishing of controlled substances in
34 violation of subdivision (a) of Section 11153.5 of the Health and
35 Safety Code. Factors to be considered in determining whether the
36 furnishing of controlled substances is clearly excessive shall
37 include, but not be limited to, the amount of controlled substances
38 furnished, the previous ordering pattern of the customer (including
39 size and frequency of orders), the type and size of the customer,
40 and where and to whom the customer distributes its product.

1 (f) The commission of any act involving moral turpitude,
2 dishonesty, fraud, deceit, or corruption, whether the act is
3 committed in the course of relations as a licensee or otherwise, and
4 whether the act is a felony or misdemeanor or not.

5 (g) Knowingly making or signing any certificate or other
6 document that falsely represents the existence or nonexistence of
7 a state of facts.

8 (h) The administering to oneself, of any controlled substance,
9 or the use of any dangerous drug or of alcoholic beverages to the
10 extent or in a manner as to be dangerous or injurious to oneself, to
11 a person holding a license under this chapter, or to any other person
12 or to the public, or to the extent that the use impairs the ability of
13 the person to conduct with safety to the public the practice
14 authorized by the license.

15 (i) Except as otherwise authorized by law, knowingly selling,
16 furnishing, giving away, or administering or offering to sell,
17 furnish, give away, or administer any controlled substance to an
18 addict.

19 (j) The violation of any of the statutes of this state or of the
20 United States regulating controlled substances and dangerous
21 drugs.

22 (k) The conviction of more than one misdemeanor or any
23 felony involving the use, consumption, or self-administration of
24 any dangerous drug or alcoholic beverage, or any combination of
25 those substances.

26 (l) The conviction of a crime substantially related to the
27 qualifications, functions, and duties of a licensee under this
28 chapter. The record of conviction of a violation of Chapter 13
29 (commencing with Section 801) of Title 21 of the United States
30 Code regulating controlled substances or of a violation of the
31 statutes of this state regulating controlled substances or dangerous
32 drugs shall be conclusive evidence of unprofessional conduct. In
33 all other cases, the record of conviction shall be conclusive
34 evidence only of the fact that the conviction occurred. The board
35 may inquire into the circumstances surrounding the commission
36 of the crime, in order to fix the degree of discipline or, in the case
37 of a conviction not involving controlled substances or dangerous
38 drugs, to determine if the conviction is of an offense substantially
39 related to the qualifications, functions, and duties of a licensee
40 under this chapter. A plea or verdict of guilty or a conviction

1 following a plea of nolo contendere is deemed to be a conviction
2 within the meaning of this provision. The board may take action
3 when the time for appeal has elapsed, or the judgment of
4 conviction has been affirmed on appeal or when an order granting
5 probation is made suspending the imposition of sentence,
6 irrespective of a subsequent order under Section 1203.4 of the
7 Penal Code allowing the person to withdraw his or her plea of
8 guilty and to enter a plea of not guilty, or setting aside the verdict
9 of guilty, or dismissing the accusation, information, or indictment.

10 (m) The cash compromise of a charge of violation of Chapter
11 13 (commencing with Section 801) of Title 21 of the United States
12 Code regulating controlled substances. The record of the
13 compromise is conclusive evidence of unprofessional conduct.

14 (n) The revocation, suspension, or other discipline by another
15 state of a license to practice pharmacy, operate a pharmacy, or do
16 any other act for which a license is required by this chapter.

17 (o) Violating or attempting to violate, directly or indirectly, or
18 assisting in or abetting the violation of or conspiring to violate any
19 provision or term of this chapter or of the applicable federal and
20 state laws and regulations governing pharmacy, including
21 regulations established by the board.

22 (p) Actions or conduct that would have warranted denial of a
23 license.

24 (q) Engaging in any conduct that subverts or attempts to
25 subvert an investigation of the board.

26 (r) The selling, trading, transferring, or furnishing of drugs
27 obtained pursuant to Section 256b of Title 42 of the United States
28 Code to any person a licensee knows or reasonably should have
29 known not to be a patient of a covered entity, as defined in
30 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
31 United States Code.

32 SEC. 4. No reimbursement is required by this act pursuant to
33 Section 6 of Article XIII B of the California Constitution because
34 the only costs that may be incurred by a local agency or school
35 district will be incurred because this act creates a new crime or
36 infraction, eliminates a crime or infraction, or changes the penalty
37 for a crime or infraction, within the meaning of Section 17556 of
38 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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